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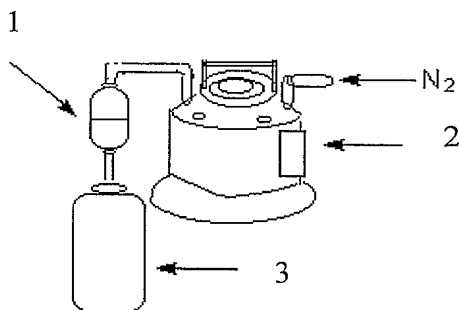
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(54) Title: PROCESS FOR THE PREPARATION OF ANHYDROUS AND HYDRATED ACTIVE PHARMACEUTICAL IN-
GREDIENTS (APIS); STABLE PHARMACEUTICAL COMPOSITIONS PREPARED FROM THE SAME AND USES OF SAID
COMPOSITIONS



(57) Abstract: This invention describes a process for the production
of ANHYDROUS active pharmaceutical ingredients (APIs); a process
for the preparation of HYDRATED active pharmaceutical ingredients, a
process for the preparation of sterile and stable injectable solutions, and
their use, more specifically, APIs which are taxane derivatives, especially
(2R,3S) 4-acetoxy-2- α -benzoyloxy-5 β -20-epoxy-1,7- β -10- β -tri-hy-
droxy-9-oxo-tax-11-en-13 α -il 3-tert-butoxycarbonylamino-2-hy-
droxy-3-phenylpropionate (I); 4-acetoxy-2- α -benzoyloxy-5 β -20-epoxy-1,
7 β -10- β -tri-hidroxy-9-oxo-tax-11-en-13 α -il (2R,3S) 3-benzoylamino-2-hy-
droxy-3-phenylpropionate (II), and particularly 4-acetoxy-2- α -benzoy-
loxy-5 β -20-epoxy-1, 7- β -10- β -tri-hidroxy-9-oxo-tax-11-en-13 α -il (2R,3S)
3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate tri-hydrate (III).

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